

JAN 10 1997

K964580

P172

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K964580

Submitted By: Jeffrey A. Dann, M.D.
President
NEBL Inc.
44 Terrace Drive
Worcester, MA 01609
Phone (508) 342-2224
Fax: (508) 345-0137

Date Prepared: 11/14/96

Device Name

Proprietary Name: NEBL, Inc. CAP-AID (Improved)

Common Name: Male Incontinence Cap

Classification Name: Penile Clamp

Substantial Equivalence

The NEBL CAP-AID (Improved) is exactly similar in indications, design and features to NEBL's original CAP-AID device.

Device Description

The CAP-AID (Improved) is exactly similar in indications, design and features to the original CAP-AID device. Only the materials are different. The material changes requested in the "Improved" version allow additional comfort and ease of use for the patient.

Intended Use

The NEBL CAP-AID (Improved) is designed to effectively occlude the male meatus thereby preventing urinary leakage.

Indications for Use

K964580
P292

The product prevents urinary leakage in men with urinary incontinence.

Substantial Equivalence Comparison

	NEBL Inc. CAP-AID (Improved)	NEBL Inc. CAP-AID (original) K954959
Indication	Prevent urine leakage in male incontinence	Prevent urine leakage in male incontinence
Mode of Operation	External device which occludes the distal urethra	External device which occludes the distal urethra
Application	1. adheres to the glans penis 2. a shallow closed ended trough occludes the meatus 3. Patient removes device to void and re-applies a new device after each void	1. adheres to the glans penis 2. a shallow closed ended trough occludes the meatus 3. Patient removes device to void and re-applies a new device after each void
Material	1. Kraton Thermoplastic elastomer G-2706 2. C-Flex Thermoplastic elastomer - CPT Technologies 3. medical grade pressure sensitive skin adhesive Dow Corning Bio PSA 7-4500	1. Kraton Thermoplastic elastomer G-2705 2. medical grade pressure sensitive skin adhesive Polyken Technologies #DFPE 170 or 3M Healthcare polyethylene film #1509
Sterility	Sterile/disposable	Sterile/disposable

The determination of substantial equivalence is not based on an assessment of any performance data, clinical or non-clinical.

Submitter's Signature



Date

11/14/86